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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/786,425	02/25/2004	Joseph A. Sorge	225436/1163	2805

27495 7590 04/11/2007
PALMER & DODGE, LLP
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BOSTON, MA 02199

EXAMINER

KAM, CHIH MIN

ART UNIT	PAPER NUMBER
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1656

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/11/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/786,425

Applicant(s)

SORGE ET AL.

Examiner

Chih-Min Kam

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 January 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1 is/are allowed.
- 6) ☒ Claim(s) 2-10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 25 February 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input checked="" type="checkbox"/> Other: <u>sequence alignment</u> . |

DETAILED ACTION

Status of the Claims

1. Claims 1-10 are pending.

Applicants' amendment filed January 22, 2007 is acknowledged. Applicant's response has been fully considered. Claims 1-10 have been amended. Therefore, claims 1-10 are examined.

Withdrawn Informalities

2. The previous objection to the specification, regarding certain sequences not having sequence identifier, is withdrawn in view of applicants' amendment to the specification in the amendment filed January 22, 2007.

Withdrawn Claim Objection

3. The previous objection to claims 1 and 5, is withdrawn in view of applicants' amendment to the claim, and applicants' response at page 5 in the amendment filed January 22, 2007.

Withdrawn Claim Rejections - 35 USC § 112

4. The previous rejection of claims 2-4 and 6-10 under 35 U. S. C. 112, second paragraph, is withdrawn in view of applicants' amendment to the claims, and applicants' response at page 5 in the amendment filed January 22, 2007.

Withdrawn Claim Rejections - 35 USC § 103

5. The previous rejection of claims 1 and 3-5 under 35 U. S. C. 103(a) as being unpatentable over Zolotukhin *et al.* (U.S. Patent 5,874,304) in view of Bryan *et al.* (U. S. Patent 6,232,107), and applicants' response at pages 5-8 in the amendment filed January 22, 2007.

New Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 2-4 and 6 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 2-4 and 6 are directed to a humanized polynucleotide, the polynucleotide encoding *R. reniformis* GFP having the sequence of SEQ ID NO:2, wherein the polynucleotide comprises SEQ ID NO:3; a recombinant vector comprising the humanized polynucleotide; a cell comprising the recombinant vector; and a method of producing *R. reniformis* GFP having the sequence of SEQ ID NO:2 using the humanized polynucleotide. While the specification indicates the present invention encompasses recombinant polynucleotides encoding the GFP from *R. reniformis*, where the polynucleotide sequence is a humanized sequence such as SEQ ID NO:3 (page 5, lines 8-10; page 6, line 23; Fig. 5; page 11, line 14-page 13, line 4; page 17, lines 9-10; Table 1 at page 50), the specification does not disclose a humanized polynucleotide encoding *R. reniformis* GFP having the sequence of SEQ ID NO:2 comprises the sequence of SEQ ID NO:3. A sequence alignment of a nucleotide sequence encoding SEQ ID NO:2 with SEQ ID NO:3 indicates SEQ ID NO:3 does not encode SEQ ID NO:2 (see attached sequence alignments; Fig 5), e.g., SEQ ID NO:2 has Val at position 56, Ser at position 131, and Asp at

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position 208, while SEQ ID NO:3 has the corresponding nucleotides encoding amino acid at position 56 are GCC (which encodes Ala), nucleotides encoding amino acid at position 131 are CGC (which encodes Arg, although Fig. 5 shows Ser at this position); and nucleotides encoding amino acid at position 208 are TAC (which encodes Tyr). The lack of description on the humanized polynucleotide encoding R. reniformis GFP having the sequence of SEQ ID NO:2 comprises SEQ ID NO:3 and lack of representative species as encompassed by the claims, applicants have failed to sufficiently describe the claimed invention, in such full, clear, concise terms that a skilled artisan would not recognize applicants were in possession of the claimed invention.

New Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 5 and 7-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 5 and 7-10 are indefinite because the claim recites a humanized polynucleotide sequence encoding R. reniformis GFP in step (a) without identifying the sequence of R. reniformis GFP and providing "SEQ ID NO:", thus it is not clear what sequence the R. reniformis GFP has. Claims 7-10 are included in the rejection because they are dependent on a rejected claim and do not correct the deficiency of the claim from which they depend.

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Conclusion

8. Claims 2-10 are rejected; and it appears that claim 1 is free of art.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

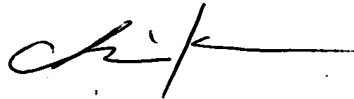
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (571) 272-0948. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Bragdon can be reached at 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Chih-Min Kam, Ph. D.
Primary Patent Examiner



CHIH-MIN KAM
PRIMARY EXAMINER

CMK

April 9, 2007

Sequence Alignment of SEQ ID NO: 2 against nucleotide sequence

ALIGNMENTS

RESULT 1

US-10-786-425-1

; Sequence 1, Application US/10786425

; GENERAL INFORMATION:

; APPLICANT: Stratagene

; TITLE OF INVENTION: Renilla Reniformis Green Fluorescent Protein and Mutants
Thereof

; FILE REFERENCE: 25436/1162

; CURRENT APPLICATION NUMBER: US/10/786,425

; CURRENT FILING DATE: 2004-02-25

; PRIOR APPLICATION NUMBER: US/09/795,040

; PRIOR FILING DATE: 2001-02-26

; PRIOR APPLICATION NUMBER: US 60/185,589

; PRIOR FILING DATE: 2000-02-28

; PRIOR APPLICATION NUMBER: 60/210,561

; PRIOR FILING DATE: 2000-06-09

; NUMBER OF SEQ ID NOS: 8

; SOFTWARE: PatentIn version 3.0

; SEQ ID NO 1

; LENGTH: 720

; TYPE: DNA

; ORGANISM: Renilla reniformis

; FEATURE:

; NAME/KEY: exon

; LOCATION: (1)..(720)

; OTHER INFORMATION: open reading frame

US-10-786-425-1

Alignment Scores:

Pred. No.:	1.52e-131	Length:	720
Score:	1253.00	Matches:	239
Percent Similarity:	100.0%	Conservative:	0
Best Local Similarity:	100.0%	Mismatches:	0
Query Match:	100.0%	Indels:	0
DB:	7	Gaps:	0

US-10-786-425-2 (1-239) x US-10-786-425-1 (1-720)

Qy	1	MetValSerLysGlnIleLeuLysAsnThrGlyLeuGlnGluIleMetSerPheLysVal	20
Db	1	ATGGTGAGTAAACAAATATTGAAGAACTGGATTGCAGGAGATCATGTCGTTTAAAGTG	60
Qy	21	AsnLeuGluGlyValValAsnAsnHisValPheThrMetGluGlyCysGlyLysGlyAsn	40
Db	61	AATCTGGAAGGTGTAGTAAACAATCATGTGTTCAATGGAAGGTTGTGGAAGGAAAT	120
Qy	41	IleLeuPheGlyAsnGlnLeuValGlnIleArgValThrLysGlyValProLeuProPhe	60
Db	121	ATTTTATTCGGAACCAACTGGTTCAGATTCGTGTACAAAAGGGTCCCCTTCATTT	180
Qy	61	AlaPheAspIleLeuSerProAlaPheGlnTyrGlyAsnArgThrPheThrLysTyrPro	80
Db	181	GCATTTGATATTCTCTCACCAGCTTTCCAATACGCAACCGTACATTACGAAATACCCG	240
Qy	81	GluAspIleSerAspPhePheIleGlnSerPheProAlaGlyPheValTyrGluArgThr	100
Db	241	GAGGATATATCAGACTTTTTTATACAATCATTTCCAGCGGGATTGTATACGAAAGAACG	300
Qy	101	LeuArgTyrGluAspGlyGlyLeuValGluIleArgSerAspIleAsnLeuIleGluGlu	120
Db	301	TTGCGTTACGAAGATGGTGGACTGGTTGAAATCCGTTTCAGATATAAATTTAATCGAGGAG	360

Qy 121 MetPheValTyrArgValGluTyrLysGlySerAsnPheProAsnAspGlyProValMet 140
 |||
 Db 361 ATGTTTGTCTACAGAGTGAATATAAAGGTAGTAACCTCCCGAATGATGGTCCAGTGATG 420
 Qy 141 LysLysThrIleThrGlyLeuGlnProSerPheGluValValTyrMetAsnAspGlyVal 160
 |||
 Db 421 AAGAAGACAATCACAGGATTACAACCTTCGTTCTGAAGTTGTGTATATGAACGATGGCGTC 480
 Qy 161 LeuValGlyGlnValIleLeuValTyrArgLeuAsnSerGlyLysPheTyrSerCysHis 180
 |||
 Db 481 TTGGTTGGCCAAGTCATTCTTGTATTATAGATTAAACTCTGGCAAATTTTATTCGTGTAC 540
 Qy 181 MetArgThrLeuMetLysSerLysGlyValValLysAspPheProGluTyrHisPheIle 200
 |||
 Db 541 ATGAGAACTGATGAAATCAAAGGGTGTAGTGAAGGATTTTCCCGAATACCATTTCATT 600
 Qy 201 GlnHisArgLeuGluLysThrAspValGluAspGlyGlyPheValGluGlnHisGluThr 220
 |||
 Db 601 CAACATCGTTTAGAGAAGACTGATGTGGAAGACGAGGTTTTGTTGAGCAACACGAGACG 660
 Qy 221 AlaIleAlaGlnLeuThrSerLeuGlyLysProLeuGlySerLeuHisGluTrpVal 239
 |||
 Db 661 GCCATTGCTCAACTGACATCGCTGGGAAACCACTTGGATCCTTACACGAATGGGTT 717

RESULT 2

US-10-786-425-3

; Sequence 3, Application US/10786425

; GENERAL INFORMATION:

; APPLICANT: Stratagene

; TITLE OF INVENTION: Renilla Reniformis Green Fluorescent Protein and Mutants
 Thereof

; FILE REFERENCE: 25436/1162

; CURRENT APPLICATION NUMBER: US/10/786,425

; CURRENT FILING DATE: 2004-02-25

; PRIOR APPLICATION NUMBER: US/09/795,040

; PRIOR FILING DATE: 2001-02-26

; PRIOR APPLICATION NUMBER: US 60/185,589

; PRIOR FILING DATE: 2000-02-28

; PRIOR APPLICATION NUMBER: 60/210,561

; PRIOR FILING DATE: 2000-06-09

; NUMBER OF SEQ ID NOS: 8

; SOFTWARE: PatentIn version 3.0

; SEQ ID NO 3

; LENGTH: 720

; TYPE: DNA

; ORGANISM: Artificial Sequence

; FEATURE:

; OTHER INFORMATION: Humanized DNA

; FEATURE:

; NAME/KEY: exon

; LOCATION: (1)..(720)

; OTHER INFORMATION: open reading frame

US-10-786-425-3

Alignment Scores:

Pred. No.:	1.64e-129	Length:	720
Score:	1235.00	Matches:	236
Percent Similarity:	98.7%	Conservative:	0
Best Local Similarity:	98.7%	Mismatches:	3
Query Match:	98.6%	Indels:	0

